In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* *		
ANNA HITT,	*	
	*	No. 15-1283V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: January 24, 2020
	*	
SECRETARY OF HEALTH	*	Entitlement, influenza ("flu") vaccine,
AND HUMAN SERVICES,	*	multiple sclerosis, transverse myelitis
	*	
Respondent.	*	
* *		

Clifford J. Shoemaker, Shoemaker, Gentry, & Knickelbein, Vienna, VA, and Renee Gentry, Washington, DC, for petitioner;
Jason C. Bougere, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED RULING ON ENTITLEMENT[1]

Anna Hitt filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 through 34 (2012) on October 29, 2015. Her petition alleged that she received the influenza ("flu") vaccine on October 23, 2014, which caused her to develop transverse myelitis and, ultimately, multiple sclerosis.[2]

The Secretary primarily opposed compensation on the grounds that Ms. Hitt experienced multiple sclerosis symptoms prior to her flu vaccination. During an entitlement hearing, the Secretary's expert effectively conceded that the flu vaccine can cause either transverse myelitis or multiple sclerosis. Because the evidence

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (http://www.cofc.uscourts.gov/aggregator/sources/7). Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

[2] Transverse myelitis is abbreviated as "TM" and multiple sclerosis to "MS."

does not support a finding that Ms. Hitt's pre-vaccination symptoms were related to her multiple sclerosis, Ms. Hitt is entitled to compensation.

I. Facts

Here, the parties largely (if not entirely) agree about the relevant events in Ms. Hitt's medical history. Consequently, the facts are presented summarily, although a more detailed recitation can be found in the parties' briefs. See Pet'r's Preh'g Br., filed Feb. 14, 2018, at 2-9; Resp't's Preh'g Br., filed Mar. 16, 2018, at 2-7.

Ms. Hitt competed in Division I college athletics. She describes herself as "very active and athletic." Exhibit 14 at 1 (Ms. Hitt's affidavit). A physical therapist similarly noted that Ms. Hitt was a "very fit young lady with [an] athletic background." Exhibit 8 at 10. After college, Ms. Hitt trained adults and children at a gym. Tr. 13. In August 2012, she received physical therapy treatment for right knee pain that had gradually arisen from "athletics/running." Exhibit 2 at 44-47.

At age 26, during a series of appointments in May and June 2013, Ms. Hitt reported having numbness, coolness, and tenderness in her right leg, extending into the toes of her right foot. Exhibit 1 at 5-9. Her doctor, Jeffrey Burnham, reached the impression that she suffered from "right leg / hip paresthesia / lumbar." Id. at 5. At a later appointment in that series, Ms. Hitt reported that she had less numbness, and the record contains no mention of coolness. Id. It appears that the problem dissipated without any medical intervention because Ms. Hitt felt well enough to join a gym in August 2013 to begin a consistent weight lighting routine for the first time since graduating from college in 2009. Exhibit 14 at 1. Prior to joining the gym, Ms. Hitt had stayed active by running and occasionally lifting weights. Tr. 17.

In September 2013, Ms. Hitt sought physical therapy treatment for a lower back injury, a lumbar strain, from lifting weights. Exhibit 2 at 17, 38. In the initial assessment of Ms. Hitt's physical impairments, the physical therapist identified flexibility, pain, range of motion, weakness, and soft tissue mobility. Id. at 11-13. Ms. Hitt appears not to have complained of numbness during this round of physical therapy. In October 2013, following overall improvement in her condition, Ms. Hitt was then discharged from physical therapy to pursue an independent home exercise program. Id. at 2-3, 5; see exhibit 8 at 10 (Ms. Hitt reported that lumbar strain in 2013 resolved with self-treatment).

More than one year later, on October 13, 2014, Ms. Hitt reported low back pain from weight lifting a week and a half earlier (approximately October 2, 2014) to Chambliss Harrod, a doctor at the Bone and Joint Clinic. Dr. Harrod described Ms. Hitt's pain as getting better but then worsening due to Ms. Hitt's continued, though somewhat restricted, weight lifting. Dr. Harrod noted "no numbness, tingling or weakness," "no neurological symptoms," and bilateral toe weakness of 4+/5 with Ms. Hitt being "slightly guarded from pain." Exhibit 9 at 52-53. From Dr. Harrod's order, Ms. Hitt saw a physical therapist to whom she again described her low back pain but noted that the pain did not have a radicular (nerve) component. Exhibit 8 at 10-11; see also exhibit 14.

As part of her participation in a nursing program, Ms. Hitt received the flu vaccine on October 23, 2014. Exhibit 13 at 2. Ms. Hitt alleges that the flu vaccine caused her subsequent neurologic problems. See Pet.

On October 29, 2014, Ms. Hitt told her physical therapist that she was having progressive numbness in both legs. She further recounted that the numbness started the previous Saturday, October 26, 2014. Exhibit 8 at 5-8. The physical therapist, in turn, communicated with Dr. Chambliss. Exhibit 9 at 31. Later on October 29, 2014, Dr. Chambliss created a note stating that Ms. Hitt had called his office and that she needs an MRI as soon as possible. Exhibit 9 at 36.[3]

On October 30, 2014, Ms. Hitt had an MRI of her lumbar spine without contrast performed. The radiologist was Robert Miller. Dr. Miller found "a 6mm nodular focus of T2 hyperintensity . . . within the distal cord, at the level of the T11-12 disc." With this information, Dr. Miller stated that "The patient will be contacted to return for additional inversion recovery sequences, to include the entire cord, followed by postcontrast imaging." Exhibit 9 at 33.

The next day, October 31, 2014, Ms. Hitt returned for additional MRIs with and without contrast. Exhibit 14 ¶ 4. The radiologist was David Hoff. For the cervical spine, Dr. Hoff identified "patchy areas of abnormal signal in the cord with expansion of the cord and edema of the cord identified at the C2, C3-C4, C5-C6, and T2 levels. Multiple patchy foci of abnormal signal in the cord are

[3] Dr. Chambliss is an orthopedist and the form he uses to order MRIs has boxes for the doctor to identify various body parts, such as "Wrist R or L" and "Pelvis." The MRI order form includes "cervical," "thoracic," and "lumbar." The form does not include "brain." Exhibit 9 at 15.

suspicious for multiple sclerosis." Exhibit 9 at 24. Following the injection of contrast, Dr. Hoff did not see any "significant enhancements." Id. In addition to stating that the appearance was "suspicious for multiple sclerosis," Dr. Hoff included transverse myelitis within the differential. Id.

The results for the thoracic spine were similar. Dr. Hoff stated: "Patchy abnormal signal in the cord can be seen at the T2 level possibly at the T6-T7 levels at the T10 level and at the T11-T12 levels." Id. at 25. Again, following the injection of contrast, Dr. Hoff did not see any "significant enhancements." Id. He interpreted these findings as "represent[ing] a demyelinating process and likely this represents multiple sclerosis." Id.[4]

Ms. Hitt recounted that she did not immediately hear from her doctor, although she was worried about the outcome of the MRIs. But, later in the evening, after she had gone to bed, the doctor called to come over to her residence. At her residence, the doctor told Ms. Hitt that she had multiple sclerosis. To address this issue, Ms. Hitt had an appointment with a neurologist for the following Monday. Exhibit 14 ¶ 5.

The first appointment with April Erwin, the neurologist who has treated Ms. Hitt, took place on November 3, 2014. Ms. Hitt informed Dr. Erwin that she had received the flu vaccine four days before the onset of symptoms. Exhibit 11 at 28. Dr. Erwin indicated that "this may be a vaccine-related event" and she provided information about the National Vaccine Injury Compensation Fund. Id. at 32. Dr. Erwin reviewed the MRIs of Ms. Hitt's spine and determined that Ms. Hitt should have an MRI of her brain. Dr. Erwin commented: "We may be able to establish an MS diagnosis without [a lumbar puncture] if she has old-appearing demyelinating lesions in the brain, to go along with the new-appearing lesions in the spinal cord." Id. Dr. Erwin also ordered a three-day course of intravenous methylprednisolone and requested that Ms. Hitt return in two to three weeks to discuss the results. Id.

The date of the brain MRI was November 20, 2014, which was nearly one month after Ms. Hitt first had symptoms of numbness on October 26, 2014. At the beginning of the MRI report, it states: "History: Question multiple sclerosis." The interpreting radiologist, Richard W. Foster, identified several "areas of altered T2 signal along with periventricular areas of altered T2 signals." "At least one lesion

[4] Dr. Hoff, in a different portion of this report, stated the finding "represents a demyelinating process possibly multiple sclerosis." Exhibit 9 at 25.

shows enhancement following contrast." Dr. Foster stated that the findings were "consistent with demyelinating disease," although Dr. Foster did not specify multiple sclerosis, transverse myelitis, or any other condition. Exhibit 11 at 26.

The follow-up appointment with Dr. Erwin occurred on the same day as the brain MRI. Dr. Erwin's history stated that "despite the initial 3-day course of SoluMedrol," Ms. Hitt reported "some upward spread of numbness on the abdomen/torso." Exhibit 11 at 20. Dr. Erwin recounted that Ms. Hitt "had no prior neurologic symptoms or events until receiving her mandatory influenza vaccine for her work as an ICU nurse. She developed symptoms of transverse myelitis within 4 days of the vaccine, with no other risks factors noted." Id.

Dr. Erwin reviewed Ms. Hitt's systems, conducted a physical examination, and reviewed the results of the brain MRI. Dr. Erwin stated that Ms. Hitt "has demyelinating lesions in both the brain and the spinal cord, indicating probable new onset MS." Dr. Erwin continued: "This fulminant demyelinating event appears to have been precipitated by influenza vaccination 4 days prior to symptom onset, as no other precipitating factor has been noted." Dr. Erwin ordered another three-day course of SoluMedrol and a lumbar puncture.

Ms. Hitt underwent a lumbar puncture on November 24, 2014. Exhibit 10 at 19. The results showed that she had five oligoclonal bands. Id. at 27.

For purposes of determining whether the flu vaccination harmed Ms. Hitt, the most recent critical event was the December 8, 2014 appointment with Dr. Erwin. Dr. Erwin stated that Ms. Hitt had a "definitive MS diagnosis . . . by McDonald criteria using MRI and CSF data." Exhibit 11 at 14. Dr. Erwin also advised Ms. Hitt "not to have influenza vaccination in the future due to complication of demyelination." Id.

After December 2014, the remainder of Ms. Hitt's medical records show how she fared with multiple sclerosis. Ms. Hitt, a trained nurse, expressed gratitude that, although she suffers from "profound numbness, loss of coordination, muscle spasticity and extreme pain, difficulty concentrating, and loss of strength," her symptoms "are mild compared to some reported by others who have been

diagnosed with MS." Exhibit 14 ¶ 8.[5] Ms. Hitt fears that a multiple sclerosis flare may take away her ability to walk. Tr. 37.

II. Procedural History

Ms. Hitt claimed that following the flu vaccine, testing confirmed that she had transverse myelitis and was later diagnosed with multiple sclerosis. Pet., filed Oct. 29, 2015, at 2 ¶ 8. The petition seeks compensation for Ms. Hitt's "losses." Pet. ¶ 10.

The Secretary filed a report, pursuant to Vaccine Rule 4, stating that Ms. Hitt's claim was not appropriate for compensation. Resp't's Rep. at 2. The Secretary argued that Ms. Hitt had not offered a substantive medical theory causally connecting the flu vaccine to transverse myelitis or multiple sclerosis. Id. at 6.

Ms. Hitt stated her intent to obtain a report from an expert. To facilitate this process, the undersigned proposed expert instructions and allowed time for the parties to comment on them. After the parties did not comment on the proposed expert instructions, they became final on April 20, 2016.

Ms. Hitt filed her first report from Dr. Carlo Tornatore on October 24, 2016. Exhibit 17. Dr. Tornatore is a neurologist and has testified in many Vaccine Program cases. Dr. Tornatore has directed the Georgetown University Hospital Multiple Sclerosis Clinic since 2000. Exhibit 68 (updated curriculum vitae). He follows thousands of patients with multiple sclerosis.

Dr. Tornatore's first report did not present a complete case. Although Dr. Tornatore cited Dr. Erwin's November 20, 2014 report in which Dr. Erwin diagnosed Ms. Hitt with "'probable new onset MS,'" exhibit 17 at 2, quoting exhibit 11 at 24, Dr. Tornatore otherwise barely mentioned multiple sclerosis. Instead, Dr. Tornatore opined that the vaccination "resulted in transverse myelitis." Exhibit 17 at 6. He explained how, in his opinion, a vaccination can cause transverse myelitis.

The Secretary filed a responsive report from Dr. Peter Donofrio on April 10, 2017. Exhibit A. Dr. Donofrio is also a neurologist. Exhibit B (curriculum vitae).

[5] Although this decision does not recount all the medical records, the undersigned has reviewed them all.

Although Dr. Donofrio has treated hundreds of patients with multiple sclerosis, but he does not specialize in treating patients with multiple sclerosis. Exhibit A at 1.

In his report, Dr. Donofrio raises three important arguments. First, he maintained that Ms. Hitt did not suffer from transverse myelitis. Instead, she suffered from multiple sclerosis. Exhibit A at 5-7. Second, Dr. Donofrio maintained that the onset of the multiple sclerosis was before the vaccination. Id. at 7. Third, Dr. Donofrio briefly asserts that the medical literature does not support a finding that the flu vaccination can cause multiple sclerosis. Id.

Both experts were directed to clarify issues from their initial reports. Dr. Tornatore was ordered to address Ms. Hitt's multiple sclerosis diagnosis, to state whether he maintains the transverse myelitis diagnosis, and to comment on Dr. Donofrio's report. Order, issued Apr. 27, 2017, at 1-3. Dr. Donofrio was also ordered to address Dr. Tornatore's main argument that the flu vaccine can cause transverse myelitis. Id. at 3-4. Shortly after this order was issued, an entitlement hearing was scheduled for April 17, 2018.

Ms. Hitt filed a second report from Dr. Tornatore on May 31, 2017. Exhibit 36. Dr. Tornatore asserted that "transverse myelitis[] can be the presenting entity in someone who is subsequently diagnosed with Multiple Sclerosis." Id. at 6. He continued to maintain that the flu vaccine can cause transverse myelitis. He also combined these two assertions, reasoning "given that transverse myelitis can be the first presentation of Multiple Sclerosis, it follows that a vaccine can trigger an immune response that ultimately can result in Multiple Sclerosis." Id. at 12.

The Secretary filed a second report from Dr. Donofrio on May 31, 2017. Exhibit C. Dr. Donofrio reiterated his view that Ms. Hitt did not meet the diagnostic criteria for transverse myelitis but did meet the criteria for multiple sclerosis. Id. at 1. Because he did not believe that Ms. Hitt can be diagnosed with transverse myelitis, Dr. Donofrio declined to address whether the flu vaccine can cause transverse myelitis. Id. at 4.

The undersigned issued an order for pre-hearing briefs on October 25, 2017. The parties were ordered to address whether transverse myelitis was the proper diagnosis of Ms. Hitt before her ultimate diagnosis of multiple sclerosis. Order, issued Oct. 25, 2017, at 4. The parties were also ordered to address the differing diagnostic criteria proposed by each side. Id.

Ms. Hitt filed her pre-hearing brief and additional medical literature on February 14, 2018. The Secretary filed his pre-hearing brief and additional medical literature on March 16, 2018.

After reviewing the parties' submissions, the undersigned conducted three pre-trial conferences. In the first pre-trial conference, the undersigned noted that Dr. Tornatore had not addressed the factors that exclude a diagnosis of transverse myelitis, notably the MRIs from October 2014. In the second pre-trial conference, Ms. Hitt's attorney made numerous statements about what the record showed but ultimately requested the opportunity to file another supplemental report from Dr. Tornatore within five days. Ms. Hitt was ordered to file a supplemental report from Dr. Tornatore promptly. Order, issued Apr. 5, 2018. Ms. Hitt punctually filed a third report from Dr. Tornatore. Exhibit 67.

In his third report, Dr. Tornatore stated that Ms. Hitt's symptoms beginning on October 26, 2014, "were solely due to spinal cord inflammation aka partial transverse myelitis." Id. at 2. He stated that because a cranial MRI was not done at the same time as the spinal MRIs, "the diagnosis of [multiple sclerosis] cannot be made or established for that point." Id. Later, Dr. Tornatore repeated and extended this point. He stated: "Neither the TM diagnostic criteria [n]or the McDonald criteria were developed to extend diagnoses to a prior period of time." Id. at 3.

After Ms. Hitt filed Dr. Tornatore's third report, the undersigned decided to proceed with the hearing. A final pre-trial conference to discuss logistics was held on April 12, 2018. The hearing took place on April 17, 2018. Because Dr. Tornatore's and Dr. Donofrio's reports constituted their direct testimony, the oral direct testimony was relatively short. Most of the hearing time was spent on answering either questions from the undersigned or questions on cross-examination.

Following the hearing, the undersigned proposed that the parties explore an informal resolution based upon the costs and risks of continued litigation. The parties attempted to reach a settlement. However, they were not successful.

After the parties reported an impasse in settlement discussion, further briefing was ordered. See order, issued Sept. 11, 2018. Ms. Hitt filed an initial brief, the Secretary filed a responsive brief, and Ms. Hitt filed a reply brief. This matter is now ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Ms. Hitt's injury claim is not included in the Vaccine Injury Table so she must establish that the flu vaccine did in fact cause her injury. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i)-(ii). Ms. Hitt must establish, by a preponderance of the evidence, the elements set forth in Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

The Secretary's objections to diagnosis and the prongs set forth in Althen, 418 F.3d at 1278, are rooted in his assertion that Ms. Hitt likely already had multiple sclerosis before she received the flu vaccination. Therefore, whether Ms. Hitt had multiple sclerosis before the vaccination will be addressed first.

A. Onset of Ms. Hitt's Demyelinating Disease

The critical factual question is whether Ms. Hitt suffered a demyelinating disease before her vaccination. If Ms. Hitt did have a demyelinating disease before vaccination, then she cannot establish that the vaccination caused the disease. Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380-81 (Fed. Cir. 2012) (ruling that if the vaccinee suffers from a disease before the vaccination, then an Althen-analysis is not required). Multiple sclerosis, for example, has been

found to afflict a vaccinee before vaccination, defeating a causation-in-fact claim. E.g. Heddens v. Sec'y of Health & Human Servs., 143 Fed. Cl. 193, 196 (2019).

While the basic definition of multiple sclerosis has not changed, the diagnostic criteria for practitioners have been revised periodically. The 2010 diagnostic criteria recognized that earlier episodes can constitute a previous demyelinating event. "Although a new attack should be documented by contemporaneous neurological examination, in the appropriate context, some historical events with symptoms and evolution characteristic for MS, but for which no objective neurological findings are documented, can provide reasonable evidence of a prior demyelinating event." Exhibit A-1 (Polman et al., Diagnostic Criteria for Multiple Sclerosis: 2010 Revisions to the McDonald Criteria, 69 Ann. Neurol. 292 (2011)) at 293 (emphasis added). The 2017 diagnostic criteria explained "typical presentations" of multiple sclerosis include "unilateral optic neuritis, focal supratentorial syndrome, focal brainstem or cerebellar syndrome or partial myelopathy." Exhibit D (Alan J. Thompson et al., Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria, 17 Lancet Neurology 162 (2018)) at 163.

Here, in their analysis of Ms. Hitt's medical records, the experts focus on four data points. These are Ms. Hitt's symptoms in May-June 2013; Ms. Hitt's symptoms in early October 2014; the results of Ms. Hitt's spinal MRIs on October 30-31, 2014; and the result of Ms. Hitt's brain MRI. For Ms. Hitt, Dr. Tornatore opined that all her pre-vaccination symptoms were not related to a demyelinating disease and that the symptoms reported on October 29, 2014, were Ms. Hitt's first neurologic symptoms related to a demyelinating disease. Tr. 91-92; 179-82. In contrast, for the Secretary, Dr. Donofrio argued that Ms. Hitt's symptoms reported at the June 3, 2013 appointment were her first multiple sclerosis attack, the symptoms reported at her October 13, 2014 appointment were her second attack, and the symptoms reported at her (first post-vaccination) appointment on October 29, 2014, were her third attack. Exhibit C at 2-3; Tr. 143.

1. Symptoms in May-June 2013.

At her June 3, 2013 appointment, Ms. Hitt reported having numbness, coolness, and tenderness in her right leg, extending into the toes of her right foot. Exhibit 1 at 6. Dr. Burnham assessed her as suffering from right "leg paresthesia." Id. at 5. In a follow-up appointment, Ms. Hitt reported that she had less numbness and there is no mention of coolness. Id. at 5. Dr. Burnham assessed Ms. Hitt as right "leg / hip paresthesias / lumbar." Id.

In interpreting Dr. Burnham's records, Dr. Tornatore stated that Ms. Hitt's symptoms reported at the June 3, 2013 appointment did not last long enough nor were they "profound" enough to qualify as a multiple sclerosis attack under the multiple sclerosis diagnostic criteria. Tr. 88-89. Dr. Tornatore also maintained that these symptoms were musculoskeletal in nature and not even neurologic. Tr. 91-92; see also Tr. 178-79. In opposition, Dr. Donofrio opined that the leg/hip paresthesia, as well as the coolness, were neurological symptoms and concluded that the symptoms signified Ms. Hitt's first episode of multiple sclerosis. Exhibit C at 2-3; Tr. 147.

While the evidence on this point is relatively close, the stronger evidence favors Ms. Hitt's position. First, Dr. Tornatore, unlike Dr. Donofrio, specializes in treating patients with multiple sclerosis. His expertise in this field merits some additional weight. See Depena v. Sec'y of Health & Human Servs., No. 13-675V, 2017 WL 1075101, at *7 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436, at *7 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016). Second, as Dr. Donofrio recognized, Dr. Burnham did not conduct a neurologic examination, such as testing reflexes. Tr. 147. In Dr. Donofrio's view, Dr. Burnham's work "would not have been a neurologic examination that would be adequate enough to come to a conclusion." Tr. 148. Thus, the evidence preponderates in favor of finding that the June 2013 episodes were not demyelinating.

2. Symptoms in early October 2014.

The other symptom Dr. Donofrio identified as an undiagnosed manifestation of multiple sclerosis came in October 2014. At Ms. Hitt's October 13, 2014 appointment, she reported low back pain from weight lifting a week and a half earlier (approximately October 2, 2014) to Chambliss Harrod. Dr. Harrod described Ms. Hitt's pain as getting better but then worsening due to Ms. Hitt's continued, though somewhat restricted, weight lifting. Dr. Harrod noted "no numbness, tingling or weakness," "no neurological symptoms," and bilateral toe weakness of 4+/5 with Ms. Hitt being "slightly guarded from pain." Exhibit 9 at 52-53. From Dr. Harrod's order, Ms. Hitt saw a physical therapist to whom she again described her low back pain, noting that the pain did not have a radicular (nerve) component. Exhibit 8 at 10-11; see also exhibit 14.

From this group of complaints, Dr. Donofrio isolated Ms. Hitt's "mild weakness of toe extension" as an indicator of a multiple sclerosis attack. Dr. Donofrio qualified his opinion in several respects. Dr. Donofrio admitted that the weakness may not show a neurologic problem and "there may not be a specific neurologic problem." Tr. 151-53. Dr. Donofrio recognized that Ms. Hitt's being "slightly guarded from pain" during the examination may have affected her toe weakness score. Tr. 151. Dr. Donofrio categorized Ms. Hitt's toe weakness as "atypical" and "unexpected." Id. 152.

Dr. Tornatore agreed that Ms. Hitt's guardedness from pain she was experiencing during the examination may have resulted in her mild toe weakness score. Tr. 180-81. Dr. Tornatore also argued that the toe weakness, and other symptoms, were not neurologic in nature because Ms. Hitt's toe strength returned to normal and her lumbar pain improved. Tr. 181-82 (discussing October 29, 2014 and November 3, 2014 appointments). The undersigned finds Dr. Tornatore's argument persuasive that Ms. Hitt's symptoms at the beginning of October 2014 were not neurologic and do not support a multiple sclerosis attack at that time.

3. Spinal MRIs.

Both experts agree that Ms. Hitt experienced a demyelinating episode on October 26, 2014. See exhibit 36 at 12, exhibit C at 3. The experts disagree on whether the MRIs taken soon after that episode show that Ms. Hitt was experiencing demyelination before the vaccination. The October 30, 2014 MRI of Ms. Hitt's lumbar spine revealed one lesion at the T11-12 disc. Exhibit 9 at 33. On October 31, 2014, Ms. Hitt had MRIs on her cervical and thoracic spine. Exhibit 9 at 24-25.[6] For both the cervical and thoracic spine, the interpreting radiologist, Dr. Hoff, found "Multiple patchy foci of abnormal signal." Id.[7]

[6] It appears that the results from the October 31, 2014 cervical spine MRI also appear at page 26.

[7] While the October 30 and 31, 2014 MRIs did not show any enhancement, Tr. 100, Dr. Donofrio has not offered any opinion that the lack of enhancement means that the lesions were sufficiently aged that the lesions must have pre-dated the vaccination. See exhibit A, exhibit C. Thus, Ms. Hitt's case is distinguishable from W.C. v. Sec'y of Health & Human Servs., No. 07-456V, 2011 WL 4537877, at *8 (Fed. Cl. Spec. Mstr. Feb. 22, 2011), mot. for rev. denied in relevant part, 100 Fed. Cl. 440, 451-53 (2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013); and Frantz v. Sec'y of Health & Human Servs., No. 13-158V, 2019 WL 3713942, at *17 (Fed. Cl. Spec.

In support of his overall opinion that Ms. Hitt suffered demyelination before the vaccination, Dr. Donofrio asserted that the "seven" lesions on Ms. Hitt's spine shown on the October 30 and 31, 2014 MRIs were "unusual." This "unusual" number, in turn, suggested that some of the lesions existed before the October 23, 2014 vaccination. Tr. 134.

While Dr. Tornatore agreed with the presence of seven lesions, he explained that the MRIs showed "edema," meaning inflammation. In his view, the edema suggested that the lesions were new and did not exist before the vaccination. Tr. 174-75. Dr. Tornatore added that for an initial demyelinating episode, a higher number of lesions all appearing together may occur and that Dr. Donofrio had not cited any literature to the contrary. Id. The diagnostic criteria for multiple sclerosis only list the minimum number of lesions needed to diagnose multiple sclerosis in different circumstances, not a maximum. Exhibit D (Thompson) at 167 / pdf 6 (Table).

4. Brain MRI.

Perhaps due to insurance company restrictions, see Tr. 44, 158; Ms. Hitt's brain MRI was performed on November 20, 2014, which was approximately one month after she first reported symptoms. This MRI showed lesions in her brain with enhancement in at least one lesion. Exhibit 11 at 26. Dr. Tornatore argued that brain MRIs allow predictions about future developments but that a brain MRI could only let you look backwards a "couple weeks." Tr. 66 Dr. Donofrio does not make an argument that the brain MRI can indicate when Ms. Hitt began to develop a demyelinating disease.

In sum, while Dr. Donofrio raised some good points, overall, Dr. Tornatore was persuasive in explaining that Ms. Hitt likely did not suffer from demyelination before the vaccination. Ms. Hitt first suffered a demyelinating episode on October 26, 2014.

As previously mentioned, Dr. Donofrio's chief reason for asserting that the vaccination did not cause Ms. Hitt's demyelinating disease was his opinion that the

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Mstr. June 24, 2019) (discussing black holes), mot. for rev. denied, 2019 WL 6974431 (Fed. Cl. Nov. 13, 2019).

disease pre-dated the vaccination. Therefore, the remaining elements of Ms. Hitt's case can be discussed relatively quickly because there is less meaningful disagreement about the remainder of the case.

B. Diagnosis

In Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the Althen test." Broekelschen's requirement that the petitioners establish, by preponderant evidence, that the vaccinee suffer the condition for which compensation is claimed is not limited to narrow circumstances. Stillwell v. Sec'y of Health & Human Servs., 118 Fed. Cl. 47, 56-58 (2014) (discussing Broekelschen and subsequent Federal Circuit cases), aff'd without opinion, 607 F. App'x 997 (Fed. Cir. 2015).

Although Dr. Tornatore and Dr. Donofrio parried over the question of diagnosis in their written reports, the experts ultimately agreed that Ms. Hitt suffered from multiple sclerosis that initially presented as transverse myelitis. Based on Ms. Hitt's onset of symptoms on October 26, 2014, and the subsequent spinal MRIs, Dr. Tornatore opined that Ms. Hitt initially developed transverse myelitis. Exhibit 67 at 2. Dr. Tornatore stated that the lack of a cranial MRI at this point made it impossible to diagnose multiple sclerosis. Id. On November 20, 2014, Ms. Hitt had a brain MRI. Based on the brain MRI findings, Dr. Tornatore stated that Ms. Hitt's multiple sclerosis diagnosis was established on November 20, 2014. Exhibit 67 at 3. In his oral testimony, Dr. Tornatore stated Ms. Hitt had "transverse myelitis, which is disease-associated, and the disease it's associated with is multiple sclerosis." Tr. 98.

Dr. Donofrio agreed with Dr. Tornatore that Ms. Hitt suffered from "transverse myelitis associated with multiple sclerosis." Tr. 142; accord Tr. 138. In sum, the weight of the evidence supports transverse myelitis as Ms. Hitt's initial diagnosis and multiple sclerosis as a subsequent diagnosis.[8]

[8] The importance of the diagnosis is diminished by Dr. Donofrio's concession that the medical theories presented by Dr. Tornatore describing how a flu vaccination could cause either transverse myelitis or multiple sclerosis are valid. Thus, regardless of which diagnosis is determined to be correct, either diagnosis would result in compensation for Ms. Hitt.

C. Medical Theory

For Althen prong one, Ms. Hitt must establish a "reputable" medical theory that the flu vaccination can cause her injury by a preponderance of the evidence but does not need to prove that theory to the level of scientific certainty. Althen, 418 F.3d at 1278 ("A persuasive medical theory . . . being supported by reputable medical or scientific explanation") (internal citations omitted). In a later case, the Federal Circuit required that the theory be "legally probable." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010).

Dr. Tornatore presented medical theories connecting the flu vaccine to transverse myelitis and multiple sclerosis. Exhibit 17 at 3-7; exhibit 36 at 12. Dr. Tornatore supported his theories with medical literature.

As noted previously, Dr. Donofrio's primary argument against causation was that Ms. Hitt had multiple sclerosis before her vaccination. Tr. 161. While Dr. Donofrio briefly disputed Dr. Tornatore's medical theories in his expert reports, exhibit A at 7 and exhibit C at 3-4, when presented with a hypothetical that Ms. Hitt never had neurological symptoms pre-vaccination, Dr. Donofrio agreed that the medical theories that flu vaccine could cause either transverse myelitis or multiple sclerosis were "valid." Tr. 166. When pressed further on cross-examination, Dr. Donofrio stated that he agreed that the flu vaccine can cause either transverse myelitis or multiple sclerosis.[9] Id. This testimony weighs heavily in petitioner's favor.

Based upon these concessions, the experts basically agree that the flu vaccine can cause a demyelinating condition. Thus, Ms. Hitt has carried her burden in establishing a medical theory.[10]

[9] In his post-hearing brief, the Secretary characterizes Dr. Tornatore's medical theories as "speculative" and "overly broad," and references Dr. Donofrio's expert reports. Resp't's Post-H'rg Br. at 1, 7. As for Dr. Donofrio's testimony regarding the hypothetical question of Ms. Hitt not having any pre-vaccination neurological symptoms, the Secretary again falls back on the position that Ms. Hitt had pre-vaccination multiple sclerosis episodes, thereby precluding vaccine causation. Id. at 8-9.

[10] Of course, in a case with different evidence, the outcome might differ. See Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1366 (Fed. Cir. 2000) ("a special master's task is to make a factual determination based on the evidence in a particular case.").

D. Logical Sequence of Cause and Effect

For Althen prong two, Ms. Hitt must establish a logical sequence of cause and effect that the flu vaccination caused her injury. Althen, 418 F.3d at 1278. Preliminarily, Ms. Hitt's case meets the basic sequence of events in that she received the vaccination and then manifested a disease.

While the vaccination must precede the onset of the disease for the vaccination to have contributed to the disease, a simple sequence of events is not sufficient. Other probative evidence may come from treating doctors. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, Ms. Hitt's treating neurologist, Dr. Erwin, supports a finding of causation. Dr. Erwin commented that "this fulminant demyelinating event appears to have been precipitated by the influenza vaccination 4 days prior to symptom onset, as no other precipitating factor had been noted." Exhibit 11 at 24. At another appointment, Dr. Erwin noted that Ms. Hitt had "no other risk factors" related to demyelinating diseases. Id. at 20. Dr. Donofrio also characterized the medical records as attributing Ms. Hitt's demyelinating disease to the flu vaccination. Exhibit A at 2. Thus, Ms. Hitt has carried her burden in establishing a logical sequence of cause and effect that the flu vaccination caused her injury.

E. Timing

For Althen prong three, Ms. Hitt must establish a proximate temporal relationship between the flu vaccination and her injury. Althen, 418 F.3d at 1278. The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

Regarding the medically acceptable timeframe for inferring causation, Dr. Tornatore proposed a range of 1 to 63 days. Exhibit 17 at 5, exhibit 36 at 11. While not addressed in his reports, Dr. Donofrio seemed to generally accept Dr. Tornatore's timeframe. Tr. 160.

As for the actual onset of the disease, Ms. Hitt received the flu vaccine on October 23, 2014, and experienced the onset of symptoms on October 26, 2014. Exhibit 8 at 5-8. Neither party disputes that these symptoms occurred on that day.

Again, the finding above that Ms. Hitt did not have any pre-vaccination demyelinating episodes supports that this day was the onset of her disease. This interval fits the range Dr. Tornatore proposed. Thus, Ms. Hitt has carried her burden in establishing a proximate temporal relationship between the flu vaccination and her injury.

V. Conclusion

Accordingly, Ms. Hitt has established that the flu vaccination was the cause-in-fact of her injury. Therefore, she is entitled to compensation under the Vaccine Act.

An order regarding damages will be issued shortly.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master